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Ms. Kristie Mikus International Trade Specialist International Trade Administration U.S. Department of Commerce 1401 Constitution Avenue, N.W., Room 4053 Washington, DC 20230

Dear Ms. Mikus:

During the question period following my testimony at the August 3 public hearing on the Commerce Department's Drug Pricing Study, I was asked why there appeared to be a discrepancy between PhRMA's estimate of annual R&D expenditure by the research-based industry in the United States, and a lower estimate by the National Science Foundation (NSF). I believe we have determined the likely reason for this discrepancy.

The NSF estimate of private spending on research and development in the pharmaceutical manufacturers (NAICS 3254) in 2001, the latest year available, came to about \$10 billion, a sharp contrast to PhRMA's 2001 figure of \$29.8 billion. The most likely source of this discrepancy is a difference in reporting standards. The NSF gets its data from a survey in which firms are asked to report and classify their R&D spending. The NSF survey specifically excludes spending on "routine product testing." Of course, product testing is an essential (and expensive) part of developing a drug.

Other NSF data supports this interpretation. The NSF itself reports the 2001 R&D spending of the top 20 firms in the U.S. (as reported by S&P). The R&D spending of the firms classified as pharmaceutical manufacturers in that list alone came to nearly \$16 billion, more than the entire industry was supposed to have spent according to the NSF survey data.

There are some further possible sources for the discrepancy. The NSF data is based on a survey, which may misestimate the level of spending by smaller firms not included in the survey (though not by larger firms, which are not sampled, but surveyed every year).

Also, the NSF classifies companies according to their largest segment. Therefore, R&D data for pharmaceutical manufacturers excludes drug research

done by firms not classified as manufacturers in the pharmaceutical industry, such as biotechs and contract research organizations (CROs).

Nonmanufacturing firms classified as "scientific R&D services" conducted \$14 billion in R&D in 2001. Though this R&D spending is still counted in a different category, those that cite NSF data often neglect this component of R&D. By further disaggregating this four digit classification code (for instance, by looking at the seven digit codes), it is highly likely that one would find significant sums of R&D expenditures being conducted for the purpose of developing medicines.

Finally, I should emphasize that PhRMA is confident that the discrepancy does not result from any misreporting of the PhRMA data. PhRMA verifies its members' responses against these publicly available reports. It is also important to highlight that the level of R&D spending is a matter of public record for public firms, and must be accurately reported for tax purposes.

I hope this information helps the Commerce Department understand the different estimates that have been developed. PhRMA would be happy to answer any additional questions you may have with respect to this issue, or any other issue that arises in the course of completing this study.

Sincerely,

Geralyn S. Ritter

Sources:

Instructions for filling out the NSF survey (see page 6):

http://www.nsf.gov/sbe/srs/sird/form2003/rd1i.pdf

Tables with spending by top 20 firms, as well as by industry:

http://www.nsf.gov/sbe/srs/seind04/c4/tt04-04.htm

http://www.nsf.gov/sbe/srs/seind04/c4/tt04-07.htm